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ABSTRACT

Prior to the enactment of the Freedom of Information Act (FOIA), little of the data collected by the Food and Drug Administration (FDA) was made public or could be obtained from the agency. Although the FDA files are now open, information is considered exempt from public disclosure when it involves regulatory procedures, program guidelines, work plans, trade secrets, pledges of confidentiality, differences of opinion, or the personnel files within a company. However, the definition of "trade secrets" (the methods or processes involved in producing a particular product) has caused great concern in the business world. Because the majority of information requests come from businesses, a number of reverse FOIA suits have focused on alleged abuses of the FOIA such as competitive harm and invasion of personal privacy. Suggested solutions to the access problem include placing the burden on the party seeking disclosure to demonstrate that the release of information is in the public interest, making the submitting party an indispensable party in FOIA suits, and permitting companies that object to the release of trade information to object in writing and allowing the requester to respond. (MAI)

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SCHOOL OF JOURNALISM, UNIVERSITY OF MISSOURI AT COLUMBIA
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ED 162 353

FREEDOM OF INFORMATION CENTER REPORT NO. 392

ACCESS TO F.D.A. INFORMATION

This report was written by Dianna Sinovic, an M.A. candidate at the University of Missouri School of Journalism.

In March 1967, a reporter for a small weekly made (Washington **Post,** 3-25-67) an appointment to visit a Food and Drug Administration official at the Crystal Plaza Building in Washington, D.C. FDA security policies required all visitors — including the press — to sign in with the receptionist in the lobby, wait until the appointment was confirmed and wear badges identifying them as visitors. Additional, impromptu visits, especially on a floor other than that approved, were prohibited.

The reporter kept his appointment at the agency but afterward, on another floor, talked to two other news sources with whom he had no appointment. An FDA information officer found the reporter in this "unauthorized area" and ordered him to leave the building immediately. The officer then called the reporter's newspaper and announced that the "welcome mat" had been removed: the reporter could no longer enter the building.

A complaint to Samuel Archibald, consultant to the House Subcommittee on Foreign Operations and Government Information, eventually resulted in the ban's being lifted. But what of access to FDA information? Has there been a change from the strict secrecy regulations such as cited above? That ban, after all, was after the passage of the Freedom of Information Act.

This report looks at what FDA information is accessible and what is still dammed behind the exemptions of the FOIA.

A Long Arm With Bulging Files

> One of the real questions that has to be answered and will be answered by the American consumer at some point in time is, "How much protection do we really want?" The closer you come to achieving 100% safety — which is impossible to achieve — the greater the price you have to pay for it. And there is some point, whether it be in products, foods or drugs, where the benefit no longer outweighs the risk and you have to say the hell with it, this is a risk we're not willing to take.[1]

The Food and Drug Administration is the long arm of the consumer, meting out approvals, snatching up recalls and setting standards for the protection of the public. The FDA must determine how dangerous a drug, food, cosmetic or — most recently — medical device is, weighing the risks involved in leaving the item on the market or in even approving the new product for sale.

The agency rides (**Christian Science Monitor,** 5-13-70) herd on a realm of 60,000 cosmetics and $130 billion annual worth of food and drugs. The bureaucratic growth as a result of burgeoning manufacturers is staggering. The FDA gathers and files away an overwhelming amount of information, much of it required: new drug applications, reports, tests, verifications. Additional data are submitted voluntarily and also stored. How much is released to the public? How much of this information that could very well affect people — drug reactions, contents of products — can be extracted from the FDA?

Surprisingly, much of the information is available if one knows what to look for and has the patience to plow through the thick mass of data the agency keeps. Once one of the most secretive of agencies, the FDA now opens many — but not all — of its files.

The controversy currently raging at the FDA pits the drug manufacturers against each other. They are concerned over FDA release of what many in the business world call "trade secrets." Instead of suing to get information under the FOIA, some companies are challenging the release with "reverse" FOIA suits. One such case, involving another federal agency, is pending in the Supreme Court; the case may establish the validity of the suit.[2]

Birth and Growth

The FDA's history dates back to Aug. 30, 1890, when Congress passed a law prohibiting the import of adulterated and unwholesome food, drugs or liquor. The FDA emerged as a full-fledged agency in 1906 with the passage of the Wiley Act, which "... prevented the manufacture, sale or transportation of adulterated, misbranded, poisonous, deleterious food, drugs, medicines and liquors and regulated traffic therein."[3]

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Summary: The Food and Drug Administration, long a bastion of secrecy prior to the FoI Act, now has opened its files—too well, some say. But it is the business world, not the public, that today is knocking at the FDA's door, requesting information that may be a "trade secret." And the barrier erected against trade secret release is the "reverse" FOIA suit, brought by the submitter of the information.

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Although the FDA — a subunit of the Department of Health, Education, and Welfare — could not stop the manufacture of such items within the states, the agency could block their introduction into interstate commerce.

In 1912 an amendment was passed prohibiting false statements on a label about the curative or therapeutic effects of a drug.

The next important step in building FDA power occurred in 1938 with the Copeland Act. The Food, Drug and Cosmetic Act — the law's formal title — added cosmetics and therapeutic devices to the list of articles under the agency's microscopic eye. A clause that later was to cause much trepidation and brow-beating added (Los Angeles **Times**, 2-18-78) the caveat that "... no (food) additive shall be deemed safe... if it is found... to induce cancer in man or animal."

Other amendments followed as more substances having undesirable effects on humans were pointed out to Congress. Insulin and antibiotics came under FDA scrutiny in 1941, prescription drugs in 1951 and pesticides in 1954. The Food Additive Amendment of 1958 required that any additive to food must be shown to be safe through "rigorous scientific testing procedures." The Color Additives Amendment of 1960 required the same for dyes and chemicals added to food.

The Drug Amendment of 1962, also known as the Kefauver-Harris Act, imposed the requirement that a drug must be proved both safe and effective to be released for market. In recent years, the amendment has come under fire from proponents of laetrile, who argue that effectiveness should not be essential to marketing a drug.

In 1972, the Drug Listing Act and the Federal Insecticide, Fungicide and Rodenticide Act were passed. The most recent legislation added medical devices to the FDA's list in 1976; this placed such items as intrauterine devices under its control. A special amendment to the FDCA last fall authorized studies on toxic and carcinogenic substances in food, such as saccharin.

Activities and Limitations

Regulation of food and drugs over the years shows the vastness of the agency's patrol. The most recent activities include recalling liquid protein products and banning fluorocarbon aerosols. Actions are often thick and furious, despite the fact that only 4,500 employees oversee tens of thousands of products. Because of the small staff, information in the FDA may be inaccurate or misused. In one example, a researcher mistakenly reported that certain spray adhesives could cause birth defects in babies. The ban was lifted several months later, but only after several doctors had recommended abortions to exposed women who were worried.

The Information Dilemma

Prior to enactment of the FOIA, very little of the wealth of data gathered by the FDA over 70-odd years was made public or could be obtained from the agency. The public had to take the agency's word that the job it was doing was adequate. Before the FOIA, the main avenue to FDA information was a request, which was usually denied, pursuant to 21 CFR section 4.1.

> Aside from such requests from attorneys, however, it was a rare day for others to seek information from the FDA files, except for congressional committees. Even with these, there was a prolonged and painful interplay before a set of informal ground rules were [sic] developed for their review of files which contained trade secrets.[4]

After the FOIA was enacted, it largely was ignored by the FDA and other federal agencies for three or four years; requests were few.

HEW issued regulations in stages and guided the FDA to its own set of rules. The FDA decided in 1971 that special regulations were needed because of the unique aspects of its power.[5] The regulations were proposed and published in 1972. The disclosure regulations adopted are the most extensive and specific FOIA guidelines ever adopted by any federal agency — in some cases, it is said, going beyond the minimum disclosure required by the act.[6]

Under the FOIA, the agency adopted a general policy:

> The Food and Drug Administration will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade secrets and confidential commercial or financial information, and the need for the agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption.[7]

Since 1975, 98 percent of the FOIA requests have been granted, with 90 percent of the files opened.[8] Information from the FDA must be requested and specifically identified. The FDA Information Center is located in Federal Office Building No. 8, 200 C St. S.W., Washington, D.C. 20204.

What Is Voluntarily Released?

The agency publishes a weekly open calendar of outside meetings and periodically publishes reports summarizing judgments, decrees and court orders handed down under the FDCA. These summaries include the nature of the charges and the disposition of the cases. A summary might contain, for example, the recall order for a certain product or a suit filed against a company for violation of the FDCA.

The agency sponsors "town meeting" forums between the commissioner and the public and has added consumer representatives to some of its advisory committees.

The FDA was the first agency to publish and distribute indexes to its information. Categories of information disclosure include flavor ingredients, environmental impact assessments, color additives, food standards, food additives, defect levels for human use, drug establishment regulations, animal drug information, new drug investigations, over-the-counter drug information, biologic reviews, cosmetic products and electronic products.[9]

Information available under the regulations includes adverse reactions to drugs (names of doctors and patients are confidential); corrective letters on drug labeling and advertising from company officials, Congress and the public; informal regulatory actions against drug and cosmetic makers; summarized plant inspections; initial drug marketing applications; operating manuals; enforcement actions and all completed reports; summarized test data (after a drug is approved); all FDA research results; safety and efficacy of many products; scientific information on new products submitted by manufacturers; and summarized marketing refusals on drugs.[10]

What Information Is Exempt?

FDA information may fall within several FOIA exemptions. Exemption two covers regulatory procedures, program guidelines, work plans and other internal instructions. Exemption three exempts material already covered by other statutes — in this case, Section 301 (j) of the FDCA, which prohibits

> . . . using by any person to his advantage, or revealing, other than to the Secretary or officers or employees of the Department or to the courts, any information acquired. . . concerning methods or processes which as a trade secret is entitled to protection.[11]

In other words, the restriction on trade secrets still stands; they cannot be disclosed.

Exemption four applies to any trade secrets obtained through means and for purposes other than those in the above statute. This exemption also includes information usually subject to a special privilege, such as doctor-patient or lawyer-client. The FDA honors this privilege. For example, the agency does not disclose the names of adverse drug reaction patients received from the medical profession, hospitals and drug manufacturers. Raw data sometimes includes the names of patients, physicians and personal information about patients. This is released only "when the need arises" — such as during a public health emergency.[12]

Any explicit or implicit pledge of confidentiality is exempt. The FDA also recognizes the "government-informer" privilege; the name of someone who reports an FDCA violation will remain confidential.[13]

Exemption five covers differences of opinion within the department, staff papers and other material flowing within the agency. Exemption six covers personnel and medical files, such as clinical information submitted by investigators, details of patient histories, and training experience and qualifications of FDA personnel.

Under exemption seven, most enforcement files and records are not disclosed. Factory inspections, sample collections and analyses, surveillance reports, warning letters and hearing notices fall into this category. Much is exempted because ". . . indiscriminate distribution of FDA investigatory files to the public would result in carte blanche interpretation of the facts in the file."[14]

Information may bypass the FOIA exemptions if the data has been disclosed previously to the public. The commissioner may make discretionary disclosures; disclosure is made if required by court order; disclosure is made to state and local government officials, consultants federal advisory boards and agencies and Congress.

The FDA makes the determination as to whether the information is exempted or not. A manufacturer may request that the information it submits be kept confidential, but it is up to the agency to make the final decision. Usually the agency will not disclose information about a product that is not on the market, or if the producers can prove that there is no intent to market the item.[15]

During product recalls, the FDA usually first contacts the company or those most directly affected, unless the recall is a "Class I" involving an emergency situation with life-threatening consequences. For example, during the recall of defective heart valves, the manufacturer was given no advance word of the action because of the seriousness of the problem.[16] Information released during a recall includes brand name, code designation and other identifying characteristics of the product.

The agency adopted a policy in 1972 to release all information submitted by drug companies and informal regulatory actions. Companies must now demonstrate that the information submitted needs to be kept secret. This policy opened up summaries of submitted test data, drugs refused approval and results of FDA research.

A rule proposed last year provides for disclosure of specifications for new human and animal drugs.[17] The rule would provide explicitly the data submitted by the manufacturer, unless no regulatory or compliance purpose is served **and** the data are exempt as trade secrets and not previously disclosed. The rule would provide assay and other analytical methods; the specifications state the characteristics established for identity, strength, quality and purity of the product.

The rule should help assure the same standards for drugs of similar type. The information is not a trade secret. Manufacturers voluntarily reveal the specifications to "official compendia" and to purchasers of the drugs; competitors may easily obtain the data because of this voluntary release.

What information is submitted to the FDA by drug manufacturers? An example of a submission form given to the FDA is the New Drug Application. Each NDA submitted to the agency must contain, by law, safety and efficacy tests; a full list of the drug components; a full statement of the drug composition; a full description of the methods, facilities and controls used in the manufacture, processing and packaging of the drug; samples of the drug and its components; and specimens of the labeling.[18]

Companies as Requesters

Opening FDA files containing data submitted by companies caused some concern in the post-FOIA (1974) days. The FDA's policy of "full agency disclosure," despite the claim of protection of private and individual interests, made some in the business world uneasy.

> . . . representatives of the regulated industry have. . . voiced concern. Some feared the FDA would modify its long-established policy of maintaining the confidentiality of most of the material contained in New Drug Applications as well as similar data obtained from other sources.[19]

The companies were concerned that the trade secret exemption might be ineffective as a means of preventing disclosure of information. But the public seldom uses the FOIA to obtain information from the FDA. In 1975, processing 13,061 FOIA requests, the FDA used the trade secret exemption only 82 times.[20] As one observer has said,

> The FDA appears from the visible record to be releasing a great deal of information. If one looks at requests that have been granted, however, it is likely that the Agency has given away only part of its vast store. The record is now too voluminous to examine. Each owner of trade secret material must make his own judgment and, if necessary, complaint.[21]

But Sen. Jacob Javits, R-N.Y., in introducing a bill to amend the FDCA in 1977, criticized the FDA for overuse of the trade secret exemption.

> I find a striking feature of the new drug approval

> process is its lack of openness. The FDA treats scientific data submitted as confidential, at least prior to approval, on claim that it constitutes a trade secret. Drug evaluation is a closed process in which all are shut out except manufacturers and certain agency consultants. The agency does not publicly announce its decisions or reasoning behind them.
>
> In a time of increasing public participation and openness in administrative decision making, the present veil of secrecy is an anachronism. Effective participation in the process is impossible without access to important safety and efficacy data.[22]

Today the primary requester of information under the FOIA is the company, not the citizen. Most of the challenges to wrongful withholding of agency information have come from the business sector, as a company attempts to extract data for an economic, competitive or legal advantage over another company. Eight out of 10 requests to the FDA come from corporations; "many are from companies trying to find out what competitors are up to."[23]

The FDA usually discloses requested information with deletions as provided by the FOIA exemptions. Yet companies claim the information remaining after deletion is still too revealing to a competitor. As William Pendergast writes, "The opportunities for obtaining information about competitors and competitive products are limited only by man's imagination."[24]

Three areas are benefited by the opportunities for disclosure: product development, comparative advertising and acquisitions.[25] Although the information on a new product is not available until after the Investigative New Drug Application is terminated, a company can obtain a summary of the safety and effectiveness data submitted. This information could help point the way for a new product, even though the data could not be submitted as the second company's data. Companies also can use the data obtained to create advertising comparing their brands to others. A company interested in buying another company could obtain the history of the company's dealings with the FDA.

What Is a Trade Secret?

What are the criteria for this exemption category? **Black's Law Dictionary** defines a trade secret as a plan or process, tool, mechanism or compound known only to its owner and those of his employees to whom it is necessary to confide it. It is any formula, pattern, device or compilation of information used in a person's business and gives the owner the opportunity to obtain an advantage over competitors who do not know or use it.[26]

Under the FDA, trade secrets might be manufacturing processes and controls, emergency permit controls, food additives, new animal and human drugs and antibiotics, insulin-containing drugs, color additives, factory inspections, inactive ingredients, and the sales, distribution, customer lists and demographic data of a company.[27]

The FDA uses wide discretion in applying the trade secret exemption. The FDA waives the exemption, as noted earlier, if the information has been disclosed lawfully elsewhere or is common knowledge. Trade secret protection also is lost if the information is not currently providing a competitive advantage, unless the manufacturer "can show in a specific factual setting that the data will provide a future competitive advantage."[28]

The FDA determines whether to release the information, sometimes with the advice of legal counsel, but not with the help of the company that submitted the data. If the information was submitted voluntarily, a presubmission review of confidentiality may be filed and a determination made by the FDA prior to actually sending in the record.[29]

If the agency rules to release the information, the company is permitted to petition to enjoin the release through a federal district court. If the FDA honors the request for confidentiality, the owner of the information is expected to defend himself in court, otherwise he waives the exemption.

One newly adopted procedure that also upsets the companies is the release of trade secrets and confidential commercial information to contractors of the FDA. The FDA considers the contractors — drug testers, for example — as intra-agency. No advance notice is given to those supplying the trade secrets under this procedure.[30]

The Reverse FOIA Suit

The legislative history of the FOIA indicates that the public and companies should not use the act to probe into sensitive company files, yet the ease with which this can be accomplished has led to precisely that result — and to the reverse FOIA suits.

Just what does such a suit involve? Thomas Patten says that

> a company whose data is threatened with release may bring what is sometimes called a "reverse FOIA" case; an action to enjoin the government from disclosing the records. This remedy can be expensive, impractical and incomplete. Because the government does not admit that a submittor of business data has a right to notice or hearing before his data is released, any theoretical legal right to prevent disclosure could be mooted by agency disclosure of the data without the submittor's knowledge. Where a submittor does have prior knowledge of a government decision to disclose its records and chooses to bring suit, it may be confident that the government will deny the submittor's right to bring such action. . . .[31]

In other words, the company will not know until after the material has been released that it will be released. Once the trade secret has been turned over to the agency, the next notice may be from the company's competitor in the form of a new product.

Several questions are raised by filing a reverse FOIA suit. Does the submitter have a right under the act to object to the disclosure? Does the submitter have the right to object under any other law? If so, what is that law's impact on the FOIA? The FOIA exemptions are permissive, not mandatory — they mark the outer limits of what **may** be withheld.[32] Disclosure may be made in spite of the exemption if release is in the public interest. This seems to prove that the submitter has no right to object to release of the information, even if that data seems to him to be confidential. The determination to release is made by the agency — and that is the real fear of business: that the agency is not equipped to make such a determination either in the time span (the 10-day limitation under the act) or in technical know-how. One observer termed the court's acceptance of FDA expertise in trade secrets and confidential information "potentially pernicious."[33]

The pending Supreme Court case involving Chrysler

Corporation and the Pentagon may clarify much of the above.

If the FDA rules against disclosure and the information seeker files suit under the FOIA, does the government have a deep enough interest in the case to adequately defend the nondisclosure? The industry does not feel that it does, according to Patten.[34]

Court Cases and Exemption Four

The standards for disclosure were set in 1974 with the **National Parks and Conservation Association v. Morton** case.[35] But several early cases addressed exemption four problems.

In one case, the company sought documents relevant to FTC rule-making proceedings, but the FTC refused to release them, claiming exemption four. A federal appeals court said the FOIA was not intended to create new loopholes in the fight for release of information. "The statutory scheme [of (b)(4)] does not permit a bare claim of confidentiality to immunize agency files from scrutiny," the court wrote.[36] Blanket exemptions are not permissible, the court said; instead, the records must be examined in camera to determine whether they actually are exempt under the trade secret clause.

In another case, an aerospace contractor sought documents from the Renegotiation Board, but the board refused under exemption four. The appellate court again ruled against the agency.

> . . . [(b)(4)] was designed to prevent the unwarranted invasions of personal privacy which might be caused by the Government's indiscriminate release of confidential information. The statutory history does not indicate, however, that Congress intended to exempt an entire document merely because it contained some confidential information.[37]

The court decided that the agency could have stricken portions of the reports to maintain the confidentiality of the sources and then released the rest.

In 1971, a citizen filed to obtain a copy of the Garwin Report, which evaluated the program development of the Supersonic Transport aircraft, held by the Office of Science and Technology. The OST claimed that it was not an agency but an advisory body to the president, and that the material was thus exempt through the intra-agency exemption. The court held that the OST was an agency, one formed to evaluate federal science programs. Material was not absolutely exempt; a determination had to be made by the court in camera as to whether it fell under the exemption.

The Standards of NATIONAL PARKS

The **National Parks** standards were based on the "competitive harm" test: Commercial and financial information is confidential and within exemption four if disclosure would be likely to cause substantial harm to the competitive position of the person submitting it.[38] No actual adverse effect on competition need be shown; the court looks at the competitive circumstances to judge the harm. This standard is called the abuse of discretion.[39] Was the release of the information arbitrary and capricious? Did it do substantial harm? Other courts have looked at two other standards, neither of them in the vein of the FOIA.[40] Was the release of information "in excess of statutory authority"? Since the FOIA exemptions are not mandatory, this cannot apply — there is no limit to authority, no absolute line that the FDA cannot cross. The third standard lies in section 1905 of Title 18, a criminal statute prohibiting employees from releasing trade secrets. But an article in **Northwestern University Law Review** said "there is at least some evidence that section 1905 is perceived as a relic of an earlier age of government secrecy."[41]

The most recent case held that there was no general right of notice to the owner of allegedly trade secret information prior to its release by the FDA.[42] This reaffirms the industry's fear that information will be released without its knowledge. Patten writes,

> The FOIA administrative scheme fails to recognize the important differences between requests for government records and for private business records. . . .the real party in interest in an Exemption 4 case is the company which submitted the data, rather than the government. The government usually has no direct interest in the secrecy of private business records and cannot be expected to protect their confidentiality as vigorously as would a truly adverse party. . . .Since the government ordinarily will not be adversely affected by disclosure, it will have little incentive to vigorously explore possible injurious consequences of disclosure to the submittor.[43]

The government also "does not possess the knowledge or expertise required to intelligently evaluate the possible competitive effects of disclosure," he says.[44] The government needs to analyze the company's cost and effort in compiling the data; understand why the data are valuable; and know the competitor's operations and market conditions before it can hope to determine adequately the status of submitted information.[45]

What Is the Answer?

One solution to the trade secret problem places the burden on the agency or party seeking disclosure to demonstrate that public interest requires the release of the confidential information.[46] Yet this would be against the intent of the act; under the 1974 amendments, the seeker no longer must give a reason for wanting the information.

Another possibility makes the submitting company an "indispensable party" in FOIA suits.[47] The company could plead more effectively against release of the information. Otherwise, the only course is to obtain a preliminary injunction immediately, in hopes that the material will not be released.

In a hearing last fall before the Government Information and Individual Rights Subcommittee, trade secret disclosures were discussed. Those opposing release stressed that government agencies should notify a company before trade information is released; that the competitive harm test should be struck down. Instead of weighing the harm from disclosure, exemption four should be mandatory. Finally, reverse FOIA suits and temporary restraining orders should be used to block disclosure.

Professor Nancy Duff Campbell of the Georgetown University Law Center advocates that a company be allowed to object in writing to the release of trade information, but that the requester be allowed to respond.[48]

On the pro-release side of the coin, Donald Kennedy of the FDA argued that a pre-release hearing would destroy the 10-day deadline under the FOIA. (Some have recommended extending this deadline to 30 days.) Kennedy also said FDA regulations are specific as to what is exempt. Only in rare cases is the confidentiality questioned; then the supplier is notified and allowed to substantiate its claim for exemption. The courts established the substantial competitive harm test for exemption four claims, and this should stand, he said.

Of course, one way to thwart the release of such information is simply not to supply it. As Pendergast says, "... companies can limit the information given to the FDA to exactly what is required and nothing more. If a trade secret does not have to go to the FDA, do not send it. What the Agency does not have, it cannot release."[49]

Access Problems Remain

> It would appear from these statistics that the FDA is giving up a substantial amount of information. Not necessarily so. The FDA's policy is to construe requests under the FOIA so as to obviate denials. If this cannot be done, the requesters are often called and the request is discussed in an effort to preclude a denial. It appears from the low number of denials that most people are satisfied with this approach. Moreover, most requests are from people sophisticated enough not to ask for exempt material.[50]

Information flows from the FDA's files, then, but in spurts. Problems in opening the files remain plentiful. Part of the reason lies in the hugeness of the agency and the vastness of its scope.

In 1970, the American Public Health Association and the National Council for Senior Citizens criticized (Louisville **Courier Journal**, 4-27-70) the FDA for failing to protect the public from dangerous, ineffective and misleadingly advertised drugs. They also charged that the FDA failed to release efficacy reports involving 4,000 drugs marketed between 1938 and 1962.

In one example of "slothargy," the FDA ruled that the chemical DES, widely used since 1954 in cattle and sheep feed to increase weight, must be removed from animal feed 48 hours before slaughter to insure that no residues reached the consumer.[51] Still, when the U.S. Department of Agriculture found DES to be a cancer-causing agent in daughters of mothers exposed to the chemical, the FDA did not ban the chemical.

One official charged (Washington **Post**, 5-1-70) the FDA with altering reports to avoid conflicts. Dr. Howard Richardson, chief pathologist in the FDA's Bureau of Science, said agency officials with little scientific background altered reports and statements. He said that information about the cancer dangers of cyclamates — as early as 1951 — was omitted from the published report; his recommendation to remove cyclamates from the market was deleted; and conclusions on the dangers of certain food additives were suppressed.

The FDA does not have the power to require compliance with safety standards, inspect a manufacturer's quality control records or see a firm's consumer complaints. The agency also has (**Christian Science Monitor**, 5-13-70) insufficient funding to do the job; only 60 to 65 percent of manufacturing plants comply with the clean plant standards, one study showed. The agency is not allowed to subpoena records or witnesses and cannot compel a company to allow a record inspection.

The FDA has been criticized for inefficiency, lack of trained personnel and politicking to stop the flow of information.

Some suggest that the FDA should allow (Des Moines **Register**, 6-7-77) citizen representatives to sit in on all drug advisory committees. Others say the FDA should permit disclosure of the existence and status of applications for new drugs or devices for approval. (Current regulations assume that the applications are confidential information and they are not even acknowledged to be at the FDA.)[52]

Dr. David Rall, a member of the Review Panel on New Drug Regulations, said (St. Louis **Globe-Democrat**, 6-1-77) that the FDA should remove the trade secret policy and add public interest representatives to the committee on drug approval.

Sen. Javits' bill, introduced last August, would make detailed summaries of data available after an agency decision is made, allow public access to data in FDA-related proceedings, and prohibit trade secret data to be used to support another drug for FDA approval.[53]

HEW Secretary Joseph Califano Jr. has called (Washington **Post**, 10-6-77) for a large-scale revision of government regulation of the drug industry. He said the FDA statute on drug approval and distribution keeps information from consumers — information necessary to decide whether they need the drugs. He urged new FDA laws to require public disclosure of drug manufacturers' scientific test information, package inserts written in plain language, a surveillance system for adverse drug reactions, and laws giving the FDA the authority to withdraw drugs when problems develop.

Conclusion

The FDA is an agency now much more open than in previous years — but only because the FOIA prompted the adoption of access rules by the agency. Whatever the reason, the FDA does allow information to flow from its files, if one has the know-how and the patience to request and, if need be, pursue the desired data.

FOOTNOTES

1. John Neary, "Eat, Drink and Be Wary," **Life**, Oct. 20, 1972, p. 81, quoting FDA Commissioner Charles Edwards.
2. "U.S. Supreme Court Agrees to Hear 'Reverse' FOIA Case," **Fol Digest**, March-April, 1978, p. 2.
3. "The Federal Food, Drug, and Cosmetic Act of 1938," **Food Drug Cosmetic Law Reports**, sec. 16, p. 4005.
4. Robert C. Brandenburg, "Information Requests Under the Fol Act," 30 Food Drug Cosmetic LJ 321 (1975).
5. Ibid., p. 322.
6. Emil Corwin, "Opening the Closed Door," **FDA Consumer**, April 1975, p. 24.
7. U.S., Department of Health, Education, and Welfare, Food and Drug Administration, "Reorganization and Republication," **Federal Register** 42, no. 55, 22 March 1977, 15617.
8. Brandenburg, p. 324.
9. Food and Drug Administration, "Reorganization and Republication," 15624.
10. **U.S. Code**, sec. 5, para. 552.
11. "Documents Requested Under Freedom of Information Act — FDA's Obligations," **Food Drug Cosmetic Law Reports**, sec. 2147, p. 5233.
12. Ibid., p. 5232.
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